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5 510(k) Summary for Mesynthes Endoform™ Reconstructive Template

1. Submitter/510(k) Holder

MAY 3 1 2013

Mesynthes Ltd
69 Gracefield Road
Lower Hutt
Wellington
New Zealand 5010

Contact Person Nancy Yopp
Telephone: +64 4 931-3512
Date Prepared: 25 February 2013

2. Device Name

Proprietary Name: Endoform™ Reconstructive Template
Common/Usual Name: Surgical Mesh
Classification Name: FTL

3. Predicate Devices

- SurgiSIS® 1- and 4-ply (Cook Biotech) (K980431)
- SIS Hernia Repair Device, SurgiSIS® Gold Hernia Repair Graft, 8-ply (Cook Biotech) (K062697)
- Strattice® LTM Surgical Mesh (LifeCell) (K070560)

4. Device Description

The Mesynthes Endoform™ Reconstructive Template (ERT) is a surgical mesh comprising either a single layer of decellularized extracellular matrix (ECM) or alternatively, multiple layers (2- to 10- layers) of ECM bonded together by dehydrothermal lamination and polyglycolic acid (PGA) suture material. The ECM component of the proposed device has received FDA clearance (K092096 and K101546) for dermal applications. The use of PGA spans a range of superficial and implantable applications including absorbable sutures (e.g. Sutrazorb® Absorbable PGA Suture, K102592) and surgical meshes (e.g. Dexon® PGA Mesh, K830889).

5. Intended Use

Endoform™ Reconstructive Template is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include, but are not limited to the following procedures; hernioplasty and repair of body wall defects. The device

allows reinforcement or bridging of a deficit to obtain the desired surgical outcome. Endoform™ Reconstructive Template is intended for single use only.

6. Technological Characteristics and Substantial Equivalence

Endoform™ Reconstructive Template and predicate devices are all primarily composed of mammalian collagens and are used for soft tissue reinforcement. They share similar indications for use, physical properties and biochemical composition. The technological characteristics of Endoform™ Reconstructive Template are substantially equivalent to other legally marketed predicate devices in terms of intended uses and indications, biological and physical performance data. Table 1 compares the ERT device and its predicates.

TABLE 5-1. Substantial Equivalence Comparison

Manufacturer	Mesynthes	Cook Biotech	Cook Biotech	LifeCell
510K Number	proposed	K980431	K062697	K070560
Device name	Endoform™ Reconstructive Template	SurgiSIS® 1- and 4-ply	SurgiSIS® 8-ply (SIS Hernia Repair Device, SurgiSIS® Gold Hernia Repair Graft)	LTM Surgical Mesh (Strattice®)
Classification	Surgical mesh (FTL) 21 CFR 878.3300 Class II	Surgical Mesh (FTM) 21 CFR 878.3300 Class II	Surgical mesh (FTL) 21 CFR 878.3300 Class II	FTM
Intended use	Endoform™ Reconstructive Template is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include, but are not limited to the following procedures; hernioplasty and repair of body wall defects. The device allows reinforcement or bridging of a deficit to obtain the desired surgical outcome. Endoform™ Reconstructive Template is intended for single use only.	SurgiSIS® is intended to be used for implantation to reinforce soft tissue. It is intended for one-time use.	The SIS Hernia Repair Device is intended to be implanted to reinforce soft tissue where weakness exists. Indications for use include the repair of a hernia and body wall defect. The device is intended for one-time use.	LTM Surgical Mesh (LTM) is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and /or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. LTM is intended for single patient use only.
Animal origin	Ovine	Porcine	Porcine	Porcine
Tissue type	Forestomach	Small intestine	Small intestine	Dermal
Nominal sizes	Variety of shapes and sizes, up to 200 cm^2	Variety of shapes and sizes, up to 400 cm^2	Variety of shapes and sizes, up to 400 cm^2	5 x 16 cm - 20 x 25 cm
Thickness	Approx. 0.15 - 1.2 mm (1-, 2-, 4-, 6-, 8- and 10-ply)	Approx. 0.1 - 0.4 mm (1- and 4-ply)	Approx. 0.8 mm (8-ply)	Approx. 1.4 mm
Presentation	Sterile, lyophilized sheets in peel pouch	Sterile lyophilized sheets in peel pouch	Sterile lyophilized sheets in peel pouch	Sterile hydrated sheets packaged in a double peel pouch configuration
Components	Ovine derived collagen and associated ECM components -collagen I -collagen III -polyglycolic acid (PGA) suture material	Porcine derived collagen and associated ECM components -collagen I -collagen III	Porcine derived collagen and associated ECM components -collagen I -collagen III	Porcine derived collagen and associated ECM components -collagen I -collagen III

7. Non Clinical Performance Testing

Testing has been carried out to demonstrate that the product meets the performance specifications for its intended use; including biocompatibility, biophysical, viral inactivation and equivalence testing.

The following biophysical tests were performed on finished, terminally sterilized product:

- Ball burst strength
- Uniaxial strength
- Suture retention strength

These tests provided evidence that Endoform™ Reconstructive Template performed similarly to its predicate devices.

The following biocompatibility tests were performed on finished sterilized product (according to ISO10993-1 standard).

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Subacute Toxicity
- Genotoxicity (Ames, chromosomal aberration and mouse lymphoma)
- Implantation

The results of these tests provided evidence that the product meets biocompatibility requirements of the ISO standard.

8. Animal Testing

In vivo studies have demonstrated the safety and effectiveness of the Endoform™ Reconstructive Template in a model of soft tissue reinforcement. The performance was substantially equivalent to the predicate device based on incorporation of the device into new tissue, inflammatory response and strength of the graft.

9. Clinical Performance Testing

There was no clinical testing required to support the indications for use as they are equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing. The verification and validation testing was found to be comparable to predicates and supports the claims of substantial equivalence, product safety and effectiveness.

10. Conclusions Drawn

Based on the testing completed and the comparisons with predicate devices, Endoform™ Reconstructive Template does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mesynthe, Ltd.
% Aptiv Solutions
Mr. Ronald Warren
11440 West Bernardo Court, Suite 300
San Diego, California 92127

May 31, 2013

Re: K130547
Trade/Device Name: Endoform™ Reconstructive Template
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: February 25, 2013
Received: March 04, 2013

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may therefore; market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K130547

Device Name: Endoform™ Reconstructive Template

Endoform™ Reconstructive Template is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include, but are not limited to the following procedures; hernioplasty and repair of body wall defects. The device allows reinforcement or bridging of a deficit to obtain the desired surgical outcome. Endoform™ Reconstructive Template is intended for single use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130547